Dissolvable Tobacco Products

Tobacco Products Scientific Advisory Committee Meeting
January 18, 2012

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DISCLAIMER: The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy. The information is being provided to TPSAC to aid the committee in its evaluation of the issues and questions referred to the committee.

Charge to the Committee*

- The Tobacco Products Scientific Advisory Committee (TPSAC) is required to review and provide recommendations to FDA regarding the "the nature and the impact of the use of dissolvable tobacco products on the public health, including such use among children."

*Section 907(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Charge to the Committee*

- TPSAC is to consider:
  - The risks and benefits to the population as a whole, including users and non-users of tobacco products;
  - The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
  - The increased or decreased likelihood that those who do not use tobacco products will start using such products.
- TPSAC report and recommendations are due March 23, 2012.

*Sections 907(a)(3)(B) and 907(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Tobacco Product

- "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."
  FD&C Act § 201(rr)(1).
- "does not mean a product that is a drug, a device, or a combination product."
  FD&C Act § 201(rr)(2).

Regulated Tobacco Products

- Currently, cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco are subject to regulation under Chapter IX. FD&C Act § 901(b).
- FDA intends to propose a regulation that would deem products meeting the statutory definition of "tobacco product" found at section 201(rr) of the FD&C Act to be subject to FDA's regulation under Chapter IX. FD&C Act § 901(b).

Smokeless Tobacco

- "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity" (FD&C Act § 900(18))."

Dissolvable Tobacco Products

- There is no statutory definition of “dissolvable tobacco product.”
- Many dissolvable tobacco products may meet the current statutory definition of “smokeless tobacco.”
- Some dissolvable tobacco products may not meet the definitions of “cigarette,” “cigarette tobacco,” “roll-your-own tobacco,” or “smokeless tobacco” and so may not currently be subject to FDA regulation under Chapter IX of the FD&C Act.

Meeting Topics

- The topic is specifically dissolvable tobacco products, not smokeless tobacco in general.

- TPSAC is **not** being asked:
  - to address use of dissolvable tobacco products as cessation aids (e.g. as a drug);
  - whether specific products are substantially equivalent to products which were on the market as of February 15, 2007;
  - at this time, to evaluate individual applications;
  - to address use of dissolvable tobacco products as potential modified risk tobacco products.

Meeting Topics Continued

- In reviewing "the nature and the impact of the use of dissolvable tobacco products on the public health…," FDA requests that TPSAC be inclusive, e.g.:
  - Without regard to whether they are currently regulated under Chapter IX (i.e., not limited to products that meet the definition of "smokeless tobacco.")

- In providing recommendations to FDA, we request that TPSAC identify the types of dissolvable tobacco products to which the advice does and does not apply.

TPSAC meeting July 21-22, 2011

- Overview of FDA Activities on Dissolvable Tobacco Products (DTPs)
  - Information Available to FDA
    - Published Peer Reviewed Literature
    - Submissions to Dockets
    - Responses to FDA's February 1, 2010 letter
    - FDA requested meetings with individual DTP manufacturers
  - FDA Research Activities
    - Consumer Perception Research
    - Quantitative Analyses
  - Other FDA Activities
    - Information Requested From Industry
      - FDA issued letters to ~125 manufacturers on June 10, 2011.http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm259009.htm

Status of Information Requested by TPSAC

- FDA has responded to TPSAC requests for information from the July 21-22, 2011 meeting:
  - Information on state and local level smoking laws in states where DTPs are thought to be marketed are provided in the background materials
  - FDA, RTI, and invited speakers will be presenting on DTPs during the January 18 – 20, 2012 meeting
  - In addition, FDA has provided information submitted by the public in the background materials

Today's Meeting

- Closed Meeting
  - Commercial confidential/trade secret industry information
  - Presentation from Altria

    FDA requested information on:
    - Design and marketing
    - Storage conditions and stability
    - Reproducibility
- Open meeting
  - Use of Swedish oral tobacco and related health effects

Clarifying Questions?